UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,559	05/02/2002	David C. Kulp	3291.7	9768

22886 7590 10/03/2005

AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
3380 CENTRAL EXPRESSWAY
SANTA CLARA, CA 95051

EXAMINER	
SMITH, CAROLYN L	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,559	KULP ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,49-51,64,65 and 67-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,49-51,64,65 and 67-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 8/12/05, has been entered.

Amended claims 19, 49-51, 64-65 and new claims 67-72, filed 8/12/05, are acknowledged.

Claims herein under examination are 19, 49-51, 64-65 and 67-72.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 49-51, 64-65 and 67-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 19 (lines 2 and 8), 49 (lines 2 and 7) and 72 (lines 2 and 7) recite the phrase "*one or more* biological probe arrays" which lacks adequate written support in the specification, claims, and/or drawings, as originally filed. Applicants provide various paragraphs of support for various claims; however, these passages do not provide support for one or more biological probe arrays. The abstract provides support for "one or more probe sets", but not one or more biological probe arrays. Because the introduction of "one or more biological probe arrays" does not appear to have adequate written support in the original application disclosure, this limitation is considered to be NEW MATTER. Claims 50-51, 64-65, and 67-71 are also rejected due to their direct or indirect dependency from claims 19 and 49.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19, 49-51, 64-65, 68, and 72 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Maslyn et al. (P/N 6,408,308).

Maslyn et al. disclose a system and method for generating, analyzing, and storing datasets from probe sequences (title). Maslyn et al. disclose a manufacturer microarray with identification of the sites having probes corresponding to a particular transcript (col. 4, lines 49-

52) which represents a probe set that is capable of identification of a biological molecule on one or more biological probe arrays, as stated in instant claims 19 and 49. Maslyn et al. disclose correlating a particular gene (biological sequence) or elements on the microarray with the probe design using microarray layout data and design data files for summarization of data (col. 6, lines 22-28). Figure 9 discloses a user defined query (530) where selected datasets are retrieved and provided based on user defined selection (531) followed by comparison (correlation) to other datasets (532/534/536/544/546) including filters to select specified elements of the dataset such as protein function (542 and col. 12, lines 11-17), ending in a viewing of the data (538). Maslyn et al. disclose filtering functions according to abundance, protein function (comparisons) as well as Figure 10A with a "build query" region with a BLAST search (sequence search) (col. 12, lines 1-5) and query parameters involving a hierarchy of enzymes including oxidoreductases and transferases (protein families) where the user can select any combination of query data across categories (col. 12, lines 32-38) and display of generated lists (col. 12, lines 39-44) which represents correlating protein sequence with protein family data and displaying information, as stated in instant claims 19 and 49. Maslyn et al. disclose a processing system with procedures and tables that store information identifying element data from microarrays (abstract) which represents an identification of the probe-set. Maslyn et al. disclose a microarray manufacturer providing data on the specific transcripts represented on the microarray and identifying the site or sites having probes corresponding to a particular transcript (col. 4, lines 49-52) including Image identifier (Image ID) as well as Sequence ID (col. 9, lines 49-55 and col. 10, lines 15-16) with displaying names of datasets resulting from a user defined query (col. 11, liens 29-41) which represents manufacture-defined probe-set identifiers with names, as stated in instant

claims 19 and 49. Maslyn et al. disclose microarray design information including data that specifies global characteristics of each microarray, array element data including sequence information, including protein sequences (col. 2, lines 19-25 and 34-39), as stated in instant claims 19 and 49. Maslyn et al. disclose correlating the elements on the microarray with the probe design (col. 6, lines 22-25). Maslyn et al. disclose microarrays generating raw image or expression data and each image data of hybridization experiments is associated with a unique Image Identifier (col. 7, line 58 to col. 8, line 3) which represents identifiers identifying probe sets from the results of one or more experiments performed using biological probe arrays, as stated in instant claims 19, 49, and 72. Maslyn et al. disclose generating data from a microarray composed of nucleic acid probe sequences representing genes or gene fragments (biological sequences) (col. 4, lines 40-43) such that each microarray represents a probe-set as well as a correlation between probe-set identifiers and genes. Maslyn et al. disclose selecting any combination of query criteria by selecting data across various categories, such as transcript, microarray (a probe-set), sample, and data source (col. 12, lines 33-38). Figure 10A discloses protein families and query parameters such as a BLAST search (593) (sequence comparison), molecular function and structural proteins (594) (protein information) (col. 11, lines 29-46 and col. 12, lines 1-2) which represents identification of a biological molecule as well as correlating sequence with protein family data via sequence similarity, as stated in instant claim 68. Maslyn et al. disclose tables that store information identifying a microarray technology type and microarray design information (abstract). Maslyn et al. disclose microarray design information includes location and sequence information (first data set) of the array elements (col. 2, lines 20-25). Maslyn et al. disclose providing probes for up to about 10,000 genes (col. 4, lines 52-56).

Maslyn et al. disclose organizing raw expression data with other user-defined data into a format suitable for loading into the expression database (col. 6, lines 9-12). Maslyn et al. disclose displaying and comparing data that is stored in external datasets (col. 12, lines 26-31). Figure 1 discloses the use of a sequence database. Merriam-Webster online dictionary defines domain as "a region distinctively marked by some physical feature", such that a structural proteins (Figure 10A) represent protein domain information, as stated in instant claims 51 and 65. Maslyn et al. disclose a protein function menu to allow users to select elements (probes) by their associated protein function (col. 1, lines 32-34 and col. 14, lines 34-36) which represents a correlation ("establish a mutual or reciprocal relation between", definition of correlate according to the Merriam-Webster online dictionary) between the microarray gene element data with the protein data. Figure 10B demonstrates datasets the user will define (602) and datasets the user will view (608). Maslyn et al. disclose generating data from a microarray composed of nucleic acid probe sequences representing genes or gene fragments (biological sequences) (col. 4, lines 40-43) such that each microarray represents a probe-set. Maslyn et al. disclose an information processing system storing expression data for polypeptide sequences (col. 2, lines 36-39). Maslyn et al. disclose correlating a particular gene (biological sequence) or elements on the microarray with the probe design using microarray layout data and design data files for summarization of data (col. 6, lines 22-28). Maslyn et al. disclose a network server, UNIX operating system, application software module, and a relational database management system (RDBMS) wherein data pass to JAVA classes such that results are displayed to the client computer (user) (col. 3, lines 39-41 and col. 4, lines 22-26; Figure 1) which represent an output manager to provide data

to user as well as an input manager, determiner, and correlator. Figure 2 shows information flowing from a database to a query to results to a users computer.

Thus, Maslyn et al. anticipate the limitations in claims 19, 49-51, 64-65, 68, and 72.

Applicants argue that Maslyn et al. do not include description of a probe array manufacturer assigned name. This statement is found unpersuasive as Maslyn et al. disclose a microarray manufacturer providing data on the specific transcripts represented on the microarray and identifying the site or sites having probes corresponding to a particular transcript (col. 4, lines 49-52) including Image identifier (Image ID) as well as Sequence ID (col. 9, lines 49-55 and col. 10, lines 15-16) with displaying names of datasets resulting from a user defined query (col. 11, liens 29-41) which represents manufacture-defined probe-set identifiers with names, as stated in instant claims 19 and 49. An Image Identifier of an array represents an assigned name. Applicants argue that Maslyn et al. do not specifically describe the nature of correlation between elements and probe design. This statement is found unpersuasive as Maslyn et al. provide various examples of comparison and correlation, as discussed in the rejection above. Applicants argue that Maslyn et al. do not describe correlating a probe set identifier comprising a name assigned by a manufacturer that specifies the probe set with a protein sequence. This statement is found unpersuasive as Maslyn et al. disclose a processing system with procedures and tables that store information identifying element data from microarrays (abstract) which represents an identification of the probe-set. Maslyn et al. disclose a microarray manufacturer providing data on the specific transcripts represented on the microarray and identifying the site or sites having probes corresponding to a particular transcript (col. 4, lines 49-52) including Image identifier

(Image ID) as well as Sequence ID (col. 9, lines 49-55 and col. 10, lines 15-16) with displaying names of datasets resulting from a user defined query (col. 11, liens 29-41). In addition, Figure 10A discloses protein families and query parameters such as a BLAST search (593) (sequence comparison), molecular function and structural proteins (594) (protein information) (col. 11, lines 29-46 and col. 12, lines 1-2). Applicants' arguments are deemed unpersuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 67 and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maslyn et al. (US 6,408,308) as applied to claims 19, 49-51, 64-65, 68, and 72 above, and further in view of Chin et al. (US 6,470,277).

Maslyn et al. describe the limitations of claims 19, 49-51, 64-65, 68, and 72 as described in the 35 USC 102 rejection above. Maslyn et al. do not describe aligning a consensus sequence, implementing a plurality of Hidden Markov Models, and correlation determination by a Hidden Markov Model value above a threshold.

Chin et al. describe performing polypeptide sequence comparisons with HMM (Hidden Markov Model) algorithms (col. 9, lines 15-17 and col. 10, lines 51-55) which is outputted to a stored database (col. 9, lines 66-67). Chin et al. describe performing HMM with the predicted protein for protein comparisons, aligning, determining the percent identity with the target and

query sequence and a consensus sequence (col. 10, line 51 to col. 11, line 5), as stated in instant claims 67-71. Chin et al. describe correlating various types of information and storing it in a format easily assessed by researchers (col. 2, lines 6-9). Chin et al. describe two or more sequences exhibit substantial sequence similarity if sequences have at least 70% amino acid residue or nucleic acid identity when compared and aligned for maximal correspondence as measured using a particular sequence comparison algorithm with probability values which are grouped as similar after examination of alignments (col. 6, line 65 to col. 7, line 25) which represents correlation determination above a threshold value, as stated in instant claim 70.

Maslyn et al. state that microarray-based experiments are generating increasing volumes of expression information that needs to be generated, stored, and provided in an effective manner (col. 2, lines 1-3). Chin et al. also state the need for techniques able to correlate various types of information and store it in a format easily assessed or queried by researchers (col. 2, lines 4-9). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to analyze protein expression microarray data (col. 2, lines 27-39) as stated by Maslyn et al. and store it with microarray design information including sequence information (col. 2, lines 20-25), such as alignments via HMM, as stated by Chin et al. (col. 6, line 65 to col. 7, line 4 and col. 7, lines 47) and via BLAST, as stated by Maslyn et al. (col. 12, lines 1-2). The person of ordinary skill in the art would have been motivated to make these modifications of various homology search algorithms with DNA and protein sequence databases (Chin et al., col. 6, lines 35-49) in order to find related sequences and further correlate information (Chin et al., col. 6, lines 35-37) that may prevent, ameliorate, or affect a variety of diseases or physiological states (Chin et al., col. 1, lines 34-36).

Therefore, Maslyn et al. in view of Chin et al. motivate the limitations of the instant invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

September 27, 2005

MARJORIE A. MORAN
PRIMARY EXAMINER
Marjorie A. Moran
9/28/05